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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|-------------------------|
| 10/664,171 | 09/16/2003 | Michi Garrison | 13854.4002 | 3332 |
| 34313 | 7590 | 11/03/2005 | | EXAMINER |
| ORRICK, HERRINGTON & SUTCLIFFE, LLP | | | | WITCZAK, CATHERINE |
| IP PROSECUTION DEPARTMENT | | | | |
| 4 PARK PLAZA | | | ART UNIT | PAPER NUMBER |
| SUITE 1600 | | | 3767 | |
| IRVINE, CA 92614-2558 | | | | DATE MAILED: 11/03/2005 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/664,171 | GARRISON ET AL. |
| | Examiner | Art Unit |
| | Catherine N. Witczak | 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/14/04; 3/10/05; 12/24/03</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 3/10/2005 contains incorrect U.S. Patent Document numbers. The respective correct numbers of the listed documents US2002/029031 and US2003/208222 are US2002/0028031 and US2003/0208222. The examiner has considered these documents, but appropriate correction is required.

Specification

2. The disclosure is objected to because of the following informalities: In the amendments to the specification filed on November 10th, 2003, *Figures 4, 5, and 6* should be changed to *Figures 5, 6, and 7* in order to correctly reflect the figures.

Appropriate correction is required.

Claim Objections

2. Claim 2 is objected to because of the following informalities: the term *extend* on line 3 should be changed to *extent*. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Simpson et al (US 6,126,635). In Figure 1, Simpson et al disclose a catheter (40) and a catheter/guidewire (12), each having a proximal and distal end. Both the catheter and catheter/guidewire have expandable occlusion devices associated therewith. Furthermore, Figure 1 discloses that the second occlusion device (20) is adapted to expand distally of the first occlusion device (48). Simpson et al also disclose that the catheter/guidewire is slidably housed within a first lumen in the catheter such that the distance between the first and second occlusion device may be varied in order to isolate an interior segment of a desired extent in column 2, lines 59-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al in view of Preissman et al (US 5728063).

In regards to claim 1, Simpson et al disclose in Figure 1 a first catheter (40) and a second catheter (12), each having a proximal and distal end. Both the first and second catheter have expandable occlusion devices associated therewith. Furthermore, Figure 1 discloses that the second occlusion device (20) is adapted to expand distally of the first occlusion device (48). Simpson et al also disclose that the second catheter is slidably housed within a first lumen in the first catheter such that the distance between the first and second occlusion device may be varied in order to isolate an interior segment of a desired extent in column 2, lines 59-67.

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In regards to claim 4, Simpson et al disclose in Figure 2 a second catheter (12) spaced from the inner wall of a first catheter (40), creating a coaxial lumen (52) surrounding a centrally located lumen (24).

Simpson et al disclose the claimed invention except for one of the catheters having a relatively stiff proximal region, a softer intermediate region and a still softer distal region. Preissman et al teach that it is known to use a relatively stiff proximal region, a softer intermediate region, and a still softer distal region in column 3, lines 17-31 to provide sufficient flexibility to permit access to tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse (column 2, lines 2-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al with a catheter with a relatively stiff proximal region, a softer intermediate region and a still softer distal region as taught by Preissman, since such a modification would provide the system with a catheter having a relatively stiff proximal region, a softer intermediate region and a still softer distal region for providing sufficient flexibility to permit access to the tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al as applied to claim 1 above, and further in view of Conway et al (US 6,102,929).

Simpson et al in view of Preissman et al disclose the claimed invention except for a pressure regulator. Conway et al teach that it is known to use a pressure regulator as set forth in column 11, lines 45-50 to provide the physician with the ability to control the pressure in the occlusion devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al and modified by Preissman et al with a pressure regulator as taught by Conway et al, since such a modification would provide the system with a pressure regulator for providing the physician with the ability to control the pressure in the occlusion devices.

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6. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al as applied to claim 1 above, and further in view of Baker et al (US 2002/0026217).

Simpson et al in view of Preissman et al disclose the claimed invention except for the second catheter having three lumens with the centrally located lumen provided with an axially extending tube. Baker et al teach that it is known to use a trilumen catheter with an axially extending tube disposed within the centrally located lumen as set forth in Figure 3 to provide a catheter with additional lumens which may be used for additional infusion devices or other purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al and modified by Preissman et al with a trilumen catheter with an axially extending tube disposed with the centrally located lumen as taught by Baker et al, since such a modification would provide a catheter with additional lumens which could be used for additional infusion devices or other purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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SUPPLY PATENT EXAMINER
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